



4164-01-P

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

**[Docket No. FDA-2019-N-0895]**

#### **Issuance of Priority Review Voucher; Material Threat Medical Countermeasure Product**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a material threat medical countermeasure (MCM) product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the 21st Century Cures Act (Cures Act), authorizes FDA to award priority review vouchers to sponsors of approved material threat MCM product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that JYNNEOS, (Smallpox and Monkeypox Vaccine, Live, Non-replicating), manufactured by Bavarian Nordic A/S, meets the criteria for a priority review voucher.

**FOR FURTHER INFORMATION CONTACT:** Shruti Modi, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

**SUPPLEMENTARY INFORMATION:** FDA is announcing the issuance of a material threat MCM priority review voucher to the sponsor of an approved material threat MCM product application. Under section 565A of the FD&C Act (21 U.S.C. 360bbb-4a), which was added by the Cures Act (Pub. L. 114-255), FDA will award priority review vouchers to sponsors of approved material threat MCM product applications that meet certain criteria upon approval of

those applications. FDA has determined that JYNNEOS (Smallpox and Monkeypox Vaccine, Live, Non-replicating), manufactured by Bavarian Nordic A/S, meets the criteria for a material threat MCM priority review voucher because it is intended to prevent smallpox infection and meets the other criteria for a material threat MCM priority review voucher. JYNNEOS is indicated for prevention of smallpox and monkeypox disease in adults 18 years of age and older determined to be at high risk for smallpox or monkeypox infection.

For further information about the material threat MCM Priority Review Voucher Program and for a link to the full text of section 565A of the FD&C Act, go to <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/mcm-related-counterterrorism-legislation>. For further information about JYNNEOS (Smallpox and Monkeypox Vaccine, Live, Non-replicating), go to the Center for Biologics Evaluation and Research Approved Vaccine Products website at <https://www.fda.gov/vaccines-blood-biologics/vaccines/approved-vaccine-products>.

**Dated:** October 2, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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